

REMARKS

Claims 12-16, 18-35, 37, 39, 41-48, 51, 53-60 and 62-63 are pending in the current application. Claim 61 has been cancelled in this Response. Claim 12 has been amended. Claims 62 and 63 are new. Support for the amendment and new claims may be found throughout the specification. Support for the amendment to Claim 12 may be found, for example, at page 7, lines 8-15. Support for Claim 62 claim may be found, for example, on page 14, lines 19-21. Support for Claim 63 may be found, for example, on page 13, lines 16-27.

Applicants expressly reserve the right to pursue cancelled subject matter in this and/or continuing applications. No new matter is added.

Claims 35, 37, 39, 41-48, 51 and 53-59 were previously withdrawn from consideration by the Examiner.

Claim Rejections under 35 USC § 112 – 2nd Paragraph

Claim 61 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 61 is cancelled herein. Applicants respectfully submit that this rejection is moot and request that this rejection be withdrawn.

Claim Rejections under 35 USC § 112 – Scope of Enablement

Claims 12, 14-16, 18-34, 60 and 61 were rejected under 35 U.S.C. § 112, first paragraph. Applicants respectfully submit that amended Claim 12 is enabled. As pending Claims 14-16, 18-34 and 60 depend from Claim 12, Applicants respectfully submit that these claims also are enabled and request that this rejection be withdrawn.

Claim Rejections under 35 USC § 102

Claims 12 was rejected under 35 U.S.C. § 102(b) as being anticipated by Payne, L.G. *et al.* (Dev. Biol. Stand. 1998. 92:79-87. "PCPP as a parenteral adjuvant for diverse antigens").

Applicants respectfully submit that amended Claim 12 is novel over Payne *et al.* and request that this rejection be withdrawn.

Claim Rejections under 35 USC § 103

Claims 14-16, 18-34, 60 and 61 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Payne, L.G. *et al.* (Dev. Biol. Stand. 1998. 92:79-87. "PCPP as a parenteral adjuvant for diverse antigens") in view of Boutriau *et al.* (WO 02/00249) and Database Medsafe NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY; 2002, GLAXOSMITHKLINE NZ LTD: "Datasheet . Hiberix" XP002306401.

The cited art does not teach each and every element recited in amended Claim 12. As pending Claims 14-16, 18-34 and 61 depend from patentable Claim 12, Applicants respectfully request that this rejection be withdrawn.

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Payne, L.G. *et al.* (Dev. Biol. Stand. 92:79-87. 1998. "PCPP as a parenteral adjuvant for diverse antigens") in view of Sanchez *et al.* (Internat. J. Pharmaceutics. 185:255-266. 1999.), Watson *et al.* (Vet. Microbiol. 34:139-153. 1993.) and Hilgers (WO 98/17310). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for at least the reason that Payne *et al.* in view of Sanchez *et al.*, Watson *et al.* and Hilgers do not include each of the claim limitations.

The Examiner acknowledges that Payne *et al.* do not teach the polyanionic polymer to be poly-L-glutamic acid (PLG). Neither Sanchez *et al.*, Watson *et al.* nor Hilgers makes up for this deficiency.

Specifically, Sanchez *et al.* do not teach "the use of PLG microspheres" as suggested by the Examiner on page 9 of the Office Action. In contrast, Sanchez *et al.* relates to formulation strategies for the stabilization of tetanus toxoid in poly(lactide-co-glycolide) (PLGA) microspheres. PLGA is not a polyanoinic polymer. Applicants' Claim 13 is directed to an immunogenic composition comprising poly-L-glutamic acid (PLG), not poly(lactide-co-glycolide) (PLGA) microspheres.

Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

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